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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE THE APPLICATION OF: Masahiro NISHIMURA, et al.	:	
	:	GROUP ART UNIT: 1617
SERIAL NO.: 10/533,659	:	EXAMINER: KAROL, JODY LYNN
FILED: May 5, 2005	:	

FOR: A COMPOSITION FOR REPAIRING INJURED SKIN

DECLARATION UNDER 37 C.F.R. §1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Now comes Makoto Kanebako who deposes and states:

1. That I am a graduate of Hoshi University and received a Ph.D. degree in Pharmacology in the year 2003.

2. That I have been employed by KOWA CO., LTD. for twenty-three years as a Researcher in the field of External Pharmaceutical.

3. That the following experiments were carried out by me or under my direct supervision and control:

Production of ointment preparation

Products of the present invention 2 and 4, and Comparative product 1:

These products were prepared by the same procedures described in Example 1 of the present specification.

Supplemental products 1 and 2:

These products were prepared in a similar manner to Example 1 of the present specification, wherein the contents of hydrogenated soybean phospholipid were 7.5% by weight (supplemental product 1) and 10.0% by weight (Supplemental product 2) respectively.

Test methods and results

According to the test methods and evaluation methods of the present specification, each ointment preparation was stored at 25°C or 40°C, and then time-dependent changes in consistency, stirring aptitude and extensibility were examined. Results are shown in Table 1.

Table 1

Component			Product of the Present Invention 2	Product of the Present Invention 4	Comparative Product 1	Supplemental Product 1	Supplemental Product 2
White soft sugar			70	70	70	70	70
Povidone-iodine			3	3	3	3	3
Macrogol 300			1	1	1	1	1
Macrogol 400			10.8	6.3	11.3	3.8	1.3
conc. Glycerol			1	1	1	1	1
1,3-Butylene glycol			1	1	1	1	1
Propylene glycol			1	1	1	1	1
Hydrogenated soybean phospholipid			0.5	5	-	7.5	10.0
Poly (oxyethylene) (160) Poly (oxypropylene) 30 Glycol			1.1	1.1	1.1	1.1	1.1
Pullulan			0.2	0.2	0.2	0.2	0.2
Potassium iodide			0.7	0.7	0.7	0.7	0.7
Citric acid			0.1	0.1	0.1	0.1	0.1
Sodium hydroxide			0.08	0.076	0.0828	0.09	0.08
Purified water			9.52	9.524	9.5172	9.52	9.52
pH	Immediately after production		4.6	4.8	4.8	4.9	4.9
Consistency (g)	Immediately after production		8.0	23.8	61.9	47.8	61.2
	1 month	25°C	10.7	25.9	191.6	64.4	91.9
		40°C	29.3	45.1	227.4	83.8	120.7
	3 month	25°C	14.5	39.1	206.5	77.9	110.4
		40°C	46.2	54.2	310.2	122.1	146.1
Stirring aptitude	Immediately after production		◎	◎	◎	◎	◎
	1 month	25°C	◎	◎	△	○	○
		40°C	◎	◎	×	○	△
	3 month	25°C	◎	◎	×	○	△
		40°C	◎	◎	×	△	△
Extensibility	Immediately after production		◎	◎	◎	◎	◎
	1 month	25°C	◎	◎	○	○	○
		40°C	◎	◎	△	○	○
	3 month	25°C	◎	◎	○	○	○
		40°C	◎	◎	△	○	○

Discussion

As is clear from Table 1, the ointment preparation containing no hydrogenated soybean phospholipid (comparative product 1) and those containing more than 5% by weight of hydrogenated soybean phospholipid (supplemental products 1 and 2) showed increased

consistencies with time and decreased stirring aptitudes and extensibilities as compared to those of the present invention (products of the present invention 2 and 4). Meanwhile, the ointment preparations of the present invention (products of the present invention 2 and 4) showed suppressed increase in consistency after being stored, and show good stirring aptitudes and extensibilities.

4. I declare under penalty of perjury under the laws of the United States of America that the foregoing is believed to be true and correct. 28 U.S.C. §1746(1)

Signature

21 October, 2008
Date